REMARKS

The applicants thank the Examiner for the thorough examination of the application. No new matter is believed to be added to the application by this Amendment.

Entry Of Amendment

Entry of this Amendment under 37 C.F.R. §1.116 is respectfully requested because it places the application in condition for allowance. Alternately, entry is requested as reducing issues for appeal.

Status Of The Claims

Claims 1-24 are pending in the application. Support for the amendments to claims 1 and 20 can be found in the specification at page 4, first paragraph; page 5, last paragraph; page 6, second paragraph; page 11, third paragraph; page 12, third paragraph and page 12, last paragraph (see also claim 7). Claims 6, 12 and 16 have been amended to improve their language.

Rejection Under 35 U.S.C. §103(a) Over Griffin

Claims 1-20 are rejected under 35 U.S.C. §103(a) as being *prima facie* obvious over the single reference of Griffin (EP 0 010 987). Claims 21-24 have not been

included in this rejection, but the Examiner has failed to acknowledge allowability of these claims. Applicants traverse.

The Present Invention And Its Advantages

The present invention pertains to preparations containing active and/or auxiliary substances, for the time- and/or dose-controllable release of these substances. These preparations contain at least two layers (a carrier layer and a matrix layer) in rolled or folded form. In one preferred embodiment of the invention, at least one layer comprises a liquid-soluble adhesive, which dissolves when the preparation is exposed to a body fluid so that the preparation can gradually unroll or unfold to yield an enhanced dosage profile.

The present invention has many embodiments, and a typical embodiment can be found in claim 1:

> 1. A preparation containing active and/or auxiliary substance(s), for the time- and/or dose-controllable release of said substances, comprising a laminate made up of at least a carrier layer (1) and a matrix layer (2), said laminate being in rolled or folded shape, wherein
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> a) the matrix layer (2) has a longitudinal extension, contains at least one active or auxiliary substance, and is continuous at least in sections thereof,
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> b) at least one of the parameters of width and concentration of the active and/or auxiliary substance of this layer is not constant in relation to said longitudinal extension, and
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> c) said carrier layer (1) is continuous and possesses a lower moisture permeability than the matrix layer (2), and
>
> wherein at least one of said layers (1, 2) comprises a liquid-soluble adhesive which dissolves when the preparation is exposed to a body fluid.

Distinctions Of The Invention Over Griffin

Distinctions of the invention over Griffin have been placed before the Examiner in the Amendment filed June 15, 2005. For brevity, these distinctions are not repeated at length here.

In the non-final Office Action of December 16, 2004, claim 7 ("wherein at least one layer is a pressure-sensitive adhesive layer") was rejected as being anticipated by Griffin. However, no specific teaching from Griffin was pointed out to support this rejection.

As discussed at page 6, second paragraph of the specification, the preparation is capable of unwinding gradually or slowly due to the presence of a liquid-soluble adhesive in at least one of the layers. The active substance release profile generates by a combination of two parameters: 1) the geometric shape of the active substance-containing layer and 2) the speed of unwinding. This mechanism of controlled release of active substance finds no disclosure in Griffin and, due to the different constitution, Griffin is incapable of providing an active substance release profile similar to the preparations of the present invention.

Also, the term "liquid soluble" pertains to the solubility in human or animal bodily fluids, such as gastric juice, intestinal fluids, etc (specification at page 6, second paragraph). More specifically, the adhesive may be a water-soluble adhesive (page 11, third paragraph, Fig. 1a). Generally, water-soluble adhesives will also be capable of being dissolved in body fluids (page 11, third paragraph). However, the claims are not restricted to water-soluble adhesives.

Also, the term "adhesive" may mean a pressure sensitive adhesive. However, the instantly amended claims encompass the broader concept of "adhesive" (pressure sensitive and not) as discussed at page 12, third paragraph of the specification (describing Fig. 4). In general, a pressure sensitive adhesive sticks to a surface and develops adhesive strength when mechanical pressure is applied. However, with respect to the present invention, this is not an essential property when selecting a suitable adhesive. As a result, the present invention can be practiced with using either a pressure sensitive adhesive or a non-pressure sensitive adhesive.

In contrast, Griffin pertains to a sustained drug release device that is rolled up and maintained in this configuration by a constraining device, e.g., adhesive backed paper strips (3), that dissolves in body fluids to allow the device to unfold (Abstract; Fig. 2; page 6, lines 13-25). After dissolution of the constraining strips, the device unrolls completely since none of the sheets (erodible sheet, resilient support member, netting envelope: Abstract; claims 1, 7, 9 and 10) contains an adhesive that might stabilize the rolled-up configuration.

Since the device of Griffin unfolds completely once the constraining device is removed by dissolution (page 6, lines 15-25), the entire length of the active substance-containing sheet becomes exposed to the environment, e.g., rumen environment, at the same time, and the device is thus not capable of generating a release profile comparable to the device of the present invention. Griffin at page 8, lines 37-38 does state: "It has been found the devices of the invention give a sustained release of medicament in the rumen . . ." However, this only means that the overall rate of active substance release is

retarded without resulting in a specific release profile. In contrast the present invention is unrolled slowly or gradually when the adhesive connecting the rolled-up laminated gradually dissolves (specification at page 6, second paragraph).

In paragraph 5 of the Office Action, the Examiner argues that, in the absence of evidence to the contrary, the device of Griffin would be expected to perform identically to that of the instant claims. As explained above, the instantly claimed invention has a function that is fundamentally different from that of Griffin. Griffin fails to teach or suggest a device that unrolls gradually. Particularly, Griffin fails to teach incorporating a liquid-soluble adhesive into at least one of the layers that form the laminate so as to control (or retard) the unwinding speed of the device. Therefore, since Griffin merely teaches a constraining device (adhesive paper strip) that results in the device unfolding completely once it is ruptured or dissolved, it is clear that Griffin's device has a fundamentally different function than the present invention as set forth in the instantly amended claims.

Further, Griffin fails to offer any teaching or suggestion that it might be advantageous to include an adhesive into one of the layers to control or retard the unwinding process of the wound-up laminate. According to Griffin, the unfolding or unwinding process is controlled either by the resilience of the erodible sheet or by the resilience of the resilient support member (page 6, line 34 to page 7, line 11).

Yet further, the Examiner is using the single reference of Griffin to allege obviousness. To establish a *prima facie* case of obviousness, "the prior art reference (or references when combined) must teach or suggest all the claim limitations." *MPEP §2143.* In addition, if a reference needs to be modified to achieve the claimed invention "there

must be a showing of a suggestion or motivation to modify the teachings of that reference to the claimed invention in order to support the obviousness conclusion." *Sibia Neurosciences Inc. v. Cadus Pharmaceutical Corp.*, 225 F.3d 1349, 55 USPQ2d 1927 (Fed. Cir. 2000).

In this case, the Examiner fails to point out a teaching or suggestion in Griffin itself pertaining to utilizing an adhesive to promote slow unwinding of the preparation.

As a result, Griffin would also fail to motivate a person having ordinary skill in the art to produce the invention of claim 1. A *prima facie* case of obviousness has thus not been made. Claims depending upon claim 1 are patentable for at least the above reasons.

This rejection is are overcome and withdrawal thereof is respectfully requested.

Information Disclosure Statement

The Examiner is thanked for considering the Information Disclosure Statement filed May 22, 2002 and for making the initialed PTO-1449 form of record in the application in the Office Action mailed December 16, 2004.

Foreign Priority

The Examiner has acknowledged foreign priority.

The Drawings

The Examiner is respectfully requested to indicate whether the drawing figures are acceptable in the next official action.

Conclusion

The Examiner's rejection has been overcome, obviated or rendered moot. No issues remain. The Examiner is accordingly respectfully requested to allow the application.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Robert E. Goozner, Ph.D. (Reg. No. 42,593) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By _____

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